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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,895	10/30/2003	Hidenori Ohki	244735US0X	7804

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EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,895

Applicant(s)

OHKI ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 9 and 12-17 is/are rejected.
- 7) ☒ Claim(s) 4-7, 10-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/25/04; 1/30/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

10695895 two nitrogens attached to the pyrazolium and has the end unit R9 as having just one N group, optionally substituted or part of a ring, while 10942916 has two separate end unit nitrogens, as R7 and R8, or R10 and R9, 10475845 has just one nitrogen attached to the pyrazolium and 10833088 does not have any N attached to the pyrazolium group, and hence these four applications present no conflicts with each other.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of bacterial infection, does not reasonably provide enablement for infections or microbes generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

These would cover any infectious disorders whatsoever, which would cover the treatment of viruses generally. No such feat has ever been accomplished. Most antivirals are effective against only one or two viruses. Although several drugs have been developed which are effective against a handful of viruses, no one has been able to get any of these antiviral drugs to work generally. There are over 400 pathogenic viruses in humans alone, with hundreds more in animals.

Thus, it now includes rotoviruses, especially the Group A type, which commonly lead to osmotic diarrhea in children. It includes calciviruses (e.g. Norwalk, Kawaii, Snow Mountain, etc)

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which cause gastroenteritis and are so poorly understood that even classification of these is considered poor. It covers measles, which can lead to croup, conjunctivitis and bacterial pneumonia. It covers astroviruses and coronaviruses, including toroviruses, which commonly cause diarrhea. It covers the very dangerous category of enteroviruses, which embrace the three polio viruses, around 30 Cocksackie viruses, a like number of echoviruses as well as other enteroviruses. These cause all manner of paralytic disorders, aseptic meningitis, pericarditis, etc, often with permanent damage or death, and are widespread. Rubella has serious implication for pregnant women. It also embraces reoviruses, which have been associated with encephalitis and pneumonia. It further embraces paramyxoviruses, especially mumps, which can cause edema, orchitis, pancreatitis, meningitis and testicular damage. It covers Parvoviruses, including B19, which can cause fifth disease and arthritis, and can exacerbate a whole range of blood disorders. It covers the Marburg virus, which can produce lesions practically anywhere in the body and Ebola, which is often deadly. It covers herpes viruses such as EBV, HHV-5, HHV-6, HHV-7, HHV-8, HVS and Simian B virus, which, is capable of infecting simian handlers, causing among other things meningoencephalitis. It covers Parainfluenza, RSV, rabies, New Castle disease, Hepatitis E, hantoviruses, and various vesiculoviruses, which can cause vesicular stomatitis. It covers alpha viruses, such as Venezuelan encephalitis or the Semliki Forest virus. It covers retroviruses such as HTLV-I, HTLV-II and FeLV. There are also dozens of phleboviruses causing a wide assortment of fevers (e.g. sandfly fever) widespread in southern Europe, middle east and Asia. Other arboviruses of some importance include various tick fevers, and Rift Valley fever. There are all manner of arboviruses which attack the CNS, including, just in the United States, SEF, EEE, WEE, and SE and numerous others elsewhere. It covers the rhinoviruses, the most common cause of the "common cold". It covers all manner of poxviruses.

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It also covers all diseases from fungi, including Histoplasmosis, Coccidioidomycosis, Blastomycosis, Paracoccidioidomycosis, Sporotrichosis, Cryptococcosis, Systemic Candidiasis, Aspergillosis, Mucormycosis, Mycetoma, Chromomycosis, and Phaeohyphomycosis . Yeasts such as *Malassezia furfur*, *Penicillium marneffei*, *Trichosporon beigelii* and *Blastoschizomyces capitatus* cause fungemia as well as focal involvement of skin and other sites. *Candida (Torulopsis) glabrata* can cause fungemia, urinary tract infections, and, occasionally, pneumonia or other focal lesions. Some species of *Fusarium* and *Scedosporium* can cause focal vasculitic lesions mimicking invasive aspergillosis.

It also covers diseases from prions (e.g. CJD), *Mycoplasma* (e.g. nonbacterial pneumonia).

Moreover, this claim language covers more than just microbes. It would also cover Parasitosis, a general category of diseases which are completely unrelated except for the fact that they arise from parasites, which are infectious organisms. These include skin diseases, such as Lice Infestations, Scabies and Leishmaniasis; ectoparasitic infestations such as Mite Infestations and Myiasis; helminthiasis including Larva Migrans, Hookworm Infections, Filariasis, Loiasis, Ascariasis, Dracunculiasis, Schistosomiasis, Onchocerciasis, Whipworm Infections, Trichinosis, and Cestode Infections (including Diphyllbothriasis, Echinococcosis and Taeniasis); intestinal diseases (including Threadworms and Pinworms) such as Dientamoebiasis, Anisakiasis and Giardiasis; protozoan infections such as Amebiasis, Blastocystis hominis infections, Malaria, Toxoplasmosis, Cryptosporidiosis, Cyclosporiasis, Babesiosis and Trypanosomiasis (including Tsetse fly and Chagas Disease) and many others. These diseases collectively affect diverse parts of the body, have very diverse mechanisms of harm and arise from unrelated organisms such as worms, flies, ticks and protozoa. It would be contrary to medical understanding for such extremely diverse diseases to be generally treatable by a single agent, and there is indeed no agent which can treat anything remotely resembling such a scope.

Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

Claims 1-3 8, 9, 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In “protected amino”, a protecting group against what? These are final products, so what is there to protect against? As there is no such thing as a universal protecting group, correct selection of a protecting group requires some knowledge of what is being protected against. Likewise for “protected hydroxy”.
2. The “for use” in claims 14-15 renders the claims unclear. Is this a method of use claim? If so, then an actual step must be recited. If not, then “for use” is just a statement of intention, a mental act, and does not limit the claim in any way, so that these two claims have the same scope as claim 1.
3. Claim 16 provides for the use of the compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 4-7, 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Mark L. Berch
Primary Examiner
Art Unit 1624**

12/9/05